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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,509	03/24/2000	Zenoviy Tkachuk	000152	2421

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EXAMINER
CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 01/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/534,509	TKACHUK, ZENOVIY	
	Examiner	Art Unit	
	Dave Nguyen	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2-5 and 25-37* is/are allowed.

6)☒ Claim(s) *1,6-24 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

It should be noted that examiner for the present application as been changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen.

Applicant's amendments filed 9-13-01 and 11-16-01 have been entered. Claims 1-5 and 20 have been amended. Claims 23-38 have been added. Claims 1-38 are pending and under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 6-19 remain rejected and claims 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the prevention of inflammation by using a composition comprising total yeast ribonucleic acid to ameliorate symptoms of inflammation, wherein said composition is administered so that said ribonucleic acid is present in the blood, does not reasonably provide enablement for treating any inflammation or inflammation-related disorder by using said composition comprising said yeast ribonucleic acid *in vivo*, wherein said composition is administered after insult. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to use the invention commensurate in scope with these claims and is repeated for the reasons set forth in the preceding Official action mailed 6-26-01 (Paper No. 3). Applicant's arguments filed 9-13-01 have been fully considered but they are not persuasive.

Claims 23 and 24 depend on claim 1. Claim 23 specifies the composition is administered by interabdominal injection. Claim 24 specifies the inflammation or inflammatory-related disorder is an acute inflammatory event involving short term effects.

Applicant argues that the specification provides RNA administration during or prior to the development of inflammatory reaction, such as in example 6 RNA is administered over 14 days after onset of inflammation (amendment, page 21). This is not found persuasive because of the reason set forth in the preceding Official action mailed 6-26-01 (Paper No. 3) and that example 6 in the specification only discloses the pathological process of adjuvant arthritis (specification, page 51) and arthritis symptom or NOS activity is observed at 14th day after the adjuvant injection (specification, page 52). All of the examples in the specification disclose injection of yeast RNA prior to the inflammation and none of these examples shows injection of total yeast RNA after inflammation alone could provide therapeutic effect in treating any inflammation or inflammation-related disorder *in vivo*. Thus, claims 1 and 6-19 remain rejected and claims 23 and 24 are rejected under 35 U.S.C. 112 first paragraph.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 20 and 38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Iyer et al., 1996 (Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 5208-5212). Applicant's amendments filed 9-13-01 and 11-16-01 necessitate this new ground of rejection.

Claim 20 is directed to a pharmaceutical composition for the treatment or prevention of inflammation or inflammatory-related disorder, wherein said composition comprising total yeast RNA and a pharmaceutically acceptable vehicle, carrier, or diluent. Claim 38 further specifies the nucleic acids contained in the composition consist essentially of said yeast total RNA.

Iyer teaches isolation of total yeast RNA from the cells of yeast strain KY114 and total RNA pellets were resuspended in water and the use of said yeast total RNA with end-labeled oligonucleotide probes for S1 nuclease analysis (e.g. p. 5209, left column). Water is considered a pharmaceutically acceptable carrier and the isolated nucleic acids in the yeast total RNA solution consist essentially of yeast total RNA. Thus, claims 20 and 38 are clearly anticipated by Iyer.

It should be noted that the intended use of a composition is a composition claim does not carry weight in 102 or 103 rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al., 1996 (Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 5208-5212). Applicant's amendments filed 9-13-01 and 11-16-01 necessitate this new ground of rejection.

Claims 20-22 are directed to a pharmaceutical composition for the treatment or prevention of inflammation or inflammatory-related disorder, wherein said composition comprising total yeast RNA and a pharmaceutically acceptable vehicle, carrier, or diluent. Claims 21 and 22 specify the ribonucleic acid has a nitrogen content of more than 14.5% by weight or has a phosphorus content of more than 8.5% by weight.

Iyer teaches isolation of total yeast RNA from the cells of yeast strain KY114 and total RNA pellets were resuspended in water and the use of said yeast total RNA with end-labeled oligonucleotide probes for S1 nuclease analysis (e.g. p. 5209, left column). Water is considered a pharmaceutically acceptable carrier.

Iyer does not teach that the ribonucleic acid has a nitrogen content of more than 14.5% by weight or has a phosphorus content of more than 8.5% by weight.

It would have been obvious for one of ordinary skill at the time of the invention to prepare a yeast total RNA having a nitrogen content that is more than 14.5% by weight or having a phosphorus content of more than 8.5% by weight since it is obvious for one of ordinary skill to prepare yeast total RNAs from various yeast strains having various nitrogen contents and phosphorus contents and the resulting isolated yeast total RNAs could have nitrogen content that is more than 14.5% by weight or have a phosphorus content of more than 8.5% by weight.

One having ordinary skill at the time the invention was made would have been motivated to prepare various yeast total RNAs having various nitrogen contents or phosphorus contents by weight in order to use said yeast total RNA with end-labeled oligonucleotide probes for S1 nuclease analysis as taught by Iyer or use for Northern blot analysis that was well known in the art with reasonable expectation of success.

Conclusion

Claims 1, 6-24 and 38 are rejected. Claims 2-5 and 25-37 are in condition for allowance.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.E.P.. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Deborah Clark

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Shin-Lin Chen, Ph.D.